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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/772,587	02/06/2004	Yasuo Morimoto	016912-0207	2342
22428	7590	01/26/2006	EXAMINER	
FOLEY AND LARDNER LLP SUITE 500 3000 K STREET NW WASHINGTON, DC 20007			COE, SUSAN D	
			ART UNIT	PAPER NUMBER
			1655	

DATE MAILED: 01/26/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 10/772,587	Applicant(s) MORIMOTO ET AL.	
	Examiner Susan D. Coe	Art Unit 1655	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 02 November 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
 4a) Of the above claim(s) 9,10,19 and 20 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-8,11-18 and 21-30 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The amendment filed November 2, 2005, has been received and entered. The text of those sections of Title 35, U.S. Code, not included in this action can be found in a prior Office action.
2. Claims 21-30 have been added.
3. Claims 1-30 are pending.
4. In the reply filed on June 24, 2005, applicant elected Group I, claims 1-8 and 11-18 (now also including claims 21-30); Bofu-tsusho-san for species A and pioglitazone for species B.
5. Claims 9, 10, 19 and 20 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on June 24, 2005.
6. Claims 1-8 and 11-18 are examined on the merits solely in regards to the elected species.

Claim Rejections - 35 USC § 112

7. Claims 1-8, 11-18 and 21-30 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention for the reasons set forth in the previous Office action.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the phrase "crude drug" is known in the art and is well defined in the art. The examiner agrees that the term "crude" is used in the art; however, it still must be clearly defined by applicant in the context of the claimed composition. Applicant has not specifically defined how the claimed herbs are extracted in order to make the

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“crude drug.” Applicant’s own arguments state that there are several ways to make a “crude drug,” i.e. cutting, crushing, drying. In addition, this term has been used in the art to refer to “crude drug” extracts with solvents. Thus, the term “crude” is used to refer to many types of drug preparations. Therefore, unless applicant’s specification clearly points out how the currently claimed “crude drugs” are made, the metes and bounds of this term are unclear.

Claim Rejections - 35 USC § 102

8. Claims 1-5, 7, 11-16, and 21-23 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 11-130686 (English language translation provided) for the reasons set forth in the previous Office action for claims 1-5, 7, and 11-16.

All of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach the claimed composition because the reference composition is not “dosed for relieving a side effect of thiazolidine compounds.” However, the prior art composition teaches using the Ephedrae, Glycyrrhizae and Gypsum in the same amounts as claimed by applicant in claim 5. Thus, the dosages used in the claimed composition are the same as the reference composition. Therefore, the reference composition is structurally the same as the claimed composition. A recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim.

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In regards to new claims 21-23, the claims require a means for providing the drug to a diabetic either with the thiazolide or before or after administration of the thiazolide. However, the thiazolide itself is not a required part of the composition. MPEP section 2183 states “The limitation in a means-plus-function claim is the overall structure corresponding to the claimed function.” The “means” for administration does not appear to structurally alter the Ephedrae, Glycyrrhizae and Gypsum composition as claimed. The “means” for administration of the pharmaceutical would be to formulate the composition as a pharmaceutical preparation, the reference teaches such a pharmaceutical preparation. Therefore, Bofu-tsusho-san as taught by the reference anticipates new claims 21-23.

Claim Rejections - 35 USC § 103

9. Claims 1, 5, 6, 11, 15, 16, 21 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-130686 for the reasons set forth in the previous Office action for claims 1, 5, 6, 11, 15, and 16.

All of applicant’s arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the reference does not teach using the composition for the same purpose as claimed. However, a person of ordinary skill in the art would still be motivated to modify the reference to optimize the beneficial effects taught by the reference. The limitations claimed by applicant are well within a reasonable range for a routine optimization. Therefore, the reference is still considered to teach the claimed invention for the reasons discussed in the previous Office action.

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10. Claims 1, 8, 11, 18, and 24-30 are rejected under 35 U.S.C. 103(a) as being unpatentable over JP 11-130686 in view of US Pat. No. 6,200,998 for the reasons set forth in the previous Office action for claims 1, 8, 11, and 18.

All of applicant's arguments regarding this ground of rejection have been fully considered but are not persuasive. Applicant argues that the anti-obesity compounds used in US '998 are structurally different from the Bofu-tsusho-san taught by JP '686; thus, a person of ordinary skill in the art would not be motivated to substitute the anti-obesity compounds of US '998 with Bofu-tsusho-san. However, JP '686 teaches using Bofu-tsusho-san to treat both obesity and diabetes. US '998 using pioglitazone for the same purpose. MPEP section 2144.06 specifically states that it is considered obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose. Thus, it is obvious to combine the composition taught by JP '686 and US '998 together because the prior art teaches using these compositions for the same purpose.

Applicant also argues that the claimed composition produces unexpected results in regards to enhancing the effects of the thiazolidine compounds while suppressing the side effect of body weight gain. However, JP '686 teaches that Bofu-tsusho-san both treats diabetes and helps lower body weight. Thus, it is expected that its combination with an additional anti-diabetic drug would improve the effects of the Bofu-tsusho-san while also retaining the weight lowering effects. Thus, the effects shown by applicant are not considered to show an unexpected property in the claimed composition.

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11. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Susan Coe whose telephone number is (571) 272-0963. The examiner can normally be reached on Monday to Thursday from 9:30 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Terry McKelvey, can be reached at (571) 272-0775. The official fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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Any inquiry of a general nature or relating to the status of this application or proceeding can be directed to the receptionist whose telephone number is (571) 272-1600.



1-12-06

Susan D. Coe
Primary Examiner
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